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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,895	07/07/2004	Robert L. Bugianesi	21013P	8858

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MERCK AND CO., INC  
P O BOX 2000  
RAHWAY, NJ 07065-0907

EXAMINER

ANDERSON, REBECCA L

ART UNIT	PAPER NUMBER
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1626

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/500,895	<b>Applicant(s)</b> BUGIANESI ET AL.	
	<b>Examiner</b> Rebecca L. Anderson	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-34 and 47 is/are pending in the application.
- 4a) Of the above claim(s) 8,10,14-19 and 28-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,11-13,20-28 and 47 is/are rejected.
- 7) ☒ Claim(s) 1-7,9,11-13,20-23 and 47 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/7/04, 5/23/05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-34 and 47 are currently pending in the instant application. Claims 1-7, 9, 11-13, 20-23 and 47 are objected. Claims 1-7, 9, 11-13, 20-28 and 47 are rejected. Claims 8, 10, 14-19 and 29-34 are withdrawn from consideration as being for non-elected subject matter.

### ***Election/Restrictions***

Applicant's election with traverse of Group VI, claims 24-28 in the reply filed on 30 March 2007 is acknowledged. The traversal is on the ground(s) that the claims satisfy the unity of invention requirement because the groups are properly linked to form a single general inventive concept. Applicant argues that the special technical feature is the core structure embodied in Formula I and all compounds share this significant common chemical structure which occupies a large portion of their structures and the compounds also possess the same utility as edg receptor agonists. This argument is not persuasive as the compounds claimed only share the common carbon linked to a 4 or 5 membered nitrogen containing heterocycle which does not occupy a large portion of their structure. Applicant argues that the technical feature defined by the examiner of is not the technical feature and that alternatives shall be considered as part of the technical feature if all alternatives are of a similar nature. Applicant argues that a Markush grouping of chemical compounds shall be regarded as being of similar nature when all alternatives have a common property and there is a significant structural element shared by all the alternatives. This is not found persuasive because the term "significant structural element is shared by all of the alternatives" refers to cases where

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the compounds share a common chemical structure which occupies a large portion of their structure or in the case of compounds which have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art. The compounds claimed only share a carbon linked to a 4 or 5 membered nitrogen containing heterocycle which does not occupy a large portion of their structure. Since the compounds have only a small portion of their structure in common, this small portion which is commonly shared was shown to not be distinct in view of the existing prior art. The instantly claimed compound has variables Ar-B-C as a large portion of the structure claimed and therefore, the compounds share only a small portion of their structures as the compound claimed also includes variables A, m, R1, R2, R3 and R4. Therefore, not only are the alternatives of the Markush grouping differently classified, but the technical feature of carbon linked to a 4 or 5 membered nitrogen containing heterocycle which occupies only a small portion of the structure has been compared to the prior art and found to not be distinct. Therefore the claims are considered to lack unity of invention as the claims are not drawn to categories of invention that are to be considered to have unity of invention as this is without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim and the technical feature of carbon linked to a 4 or 5 membered nitrogen containing heterocycle is not distinct over the prior art.

However, upon further consideration, the products of the formula (I), found in claims 1-7, 9, 11-13, 20-23 and 47, wherein Ar is phenyl; A is  $-\text{CO}_2\text{H}$ ; R1 and R2 are each independently selected from the group consisting of hydrogen and C1-4alkyl; C is

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thienyl substituted with 1-3 substituents independently selected from the group consisting of halo, phenyl or C1-4alkyl substituted from one up to the maximum number of substitutable positions with a halo; and B is C1-5alkoxy are hereby rejoined with elected Group VI.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Objections***

Claims 23 and 28 are objected to because of the following informalities: Claims 23 and 28 do not end in a period. Appropriate correction is required.

Claims 1-7, 9, 11-13, 20-23 and 47 are objected to as containing non-elected subject matter. Claims 1-7, 9, 11-13, 20-23 and 47 presented drawn solely to the elected invention as identified supra would overcome this objection.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 47 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23 and 24 of copending Application No. 10/501,176. Although the conflicting claims are not identical, they are not patentably distinct from each other because conflicting claims 23 and 24 claim a composition comprising a compound which is an agonist of the S1P1/Edg1 receptor in an amount effective for treating an immunoregulatory abnormality, wherein said compound possesses a selectivity for the S1P1/Edg1 receptor over the S1Pr3/Edg3 receptor of at least 20 or 100 fold as measured by the ration of EC50 for the S1P1/Edg1 receptor to the EC50 for the S1P3/Edg3 receptor as evaluated in the 35-GTPgS binding assay and wherein said compound possesses an EC50 for binding to the S1P1/Edg1 receptor of 100nM or 10 nM or less as evaluated by the 35-GTPgS binding assay. Page 13 or the

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specification of 10/501,176 provides a table of exemplary compounds which have this activity and pages 14-17 disclose specific compounds which are species within applicants' instantly claimed invention which have this activity and are exemplified as preferred embodiments in the 10/501,176 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 9, 11-13, 20-28 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/38325.

***Determining the scope and contents of the prior art***

WO 01/38325 provides hypoglycemic and hypolipidemic active products (abstract) such as the formula (I), page 3, which overlaps with applicants' instantly claimed product. Preferences towards applicants' instantly claimed invention can be seen in the preferred embodiments, such as wherein R1 is thienyl substituted with phenyl, halo or alkyl substituted with halo (page 11, page 12, page 14, page 23 and 24); X is preferably a bond (page 24); m is more preferably 1 to 2 (page 25); Y is preferably an oxygen atom (page 25); A is preferably a benzene ring (page 27); n is preferably 1 to 3 (page 27); B is seen in preferred examples as pyrrolidine (page 28); W is preferably –CH<sub>2</sub>– (page 33); R3 is preferably –OR<sub>8</sub> wherein R<sub>8</sub> is hydrogen (page 34).

***Ascertaining the differences between the prior art and the claims at issue***

The difference between the prior art and the claims at issue is that while the prior art provides products which overlap with applicant's instantly claimed invention and provides preferences towards applicants instantly claimed invention, the prior art does not prepare a species within applicants' instantly claimed invention.

***Resolving the level of ordinary skill in the pertinent art***

However, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare products as instantly claimed when faced with the prior art of



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WO 01/38325 since WO 01/38325 provides products which overlap with applicants' instantly claimed invention and provides preferences towards applicants' instantly claimed invention. The motivation would be the high expectation of preparing additional products with hypoglycemic and hypolipidemic activity.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday from 6:00am until 2:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Rebecca Anderson/  
Primary Examiner, AU 1626*

1 June 2007

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Rebecca Anderson  
Primary Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600